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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/685,830	10/09/2000	Alexander Gaiger	210121.465C3	4595

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/685,830	GAIGER ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 56,57 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 56,57 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Applicant's election with traverse of non specific immune response enhancer in the reply filed on 9/29/04 is acknowledged. The traversal is on the ground(s) that are stated. This is not found persuasive because the searching of additional species would place a serious burden on the Examiner and the species are distinct for the reasons elaborated in the previous Office Action.

The requirement is still deemed proper and is therefore made FINAL.

2. Applicant's election of WT1 peptide greater than 249 amino acids in the reply filed on 9/8/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 56 and 57 are under consideration.

4. The rejection of claims 47,50,53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in a previous Office Action is withdrawn in view of the cancellation of said claims.

5. The rejection of claims 16-18,47,50,53 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons elaborated in a previous Office Action is withdrawn in view of the cancellation of said claims.

6. The rejection of claim 17 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in a previous Office Action is withdrawn in view of the cancellation of said claim.

7. The rejection of claims 16-18,24,47,50,53 under 35 U.S.C. 102(a) or 102(e) as being anticipated by Chada et al. (US Patent 5,693,522) as evidenced by Berzofsky et al. for the reasons elaborated in a previous Office Action is withdrawn in view of the cancellation of said claims.

8. The rejection of claims 16,18,24,47,50,53 under 35 U.S.C. 102(b) as being anticipated by Berzofsky et al. (WO 94/21287) for the reasons elaborated in a previous Office Action is withdrawn in view of the cancellation of said claims.

9. The rejection of claims 16,18,24,47,50,53 under 35 U.S.C. 103(a) as being unpatentable over Chada et al. in view of Herlyn et al. (WO 95/29995) for the reasons elaborated in a previous Office Action is withdrawn in view of the cancellation of said claims.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 56 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the peptide recited in claim 56, part (a). Regarding applicants comments, none of the cited passages of the specification disclose the scope of the aformentioned peptide wherein it encompasses any peptide from WT1 that is 249 amino acids or longer, but less than full length. There is no written descritpion of the scope of the claimed invention in the specification as originally filed (aka the claimed inventions constitute new matter).

There is no support in the specification as originally filed for the recitation of "lipid A derived protein". Regarding applicants comments, in the cited sentence of the specification , page 16, the "derived proteins" refers to *Bortadella* and *Mycobacterim.* Lipid A is a lipid, not a protein (see Wikipedia citation).

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chada et al. (US Patent 5,693,522) in view of Herlyn et al. (WO 95/29995).

Chada et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (see column 1, second paragraph, column 2, column 4, second paragraph, and last paragraph, continued on column 5, column 8, column 14, last two paragraphs and column 15). Chada et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see column 15, second paragraph). Chada et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (see column 15, third paragraph). The peptide taught by Chada et al encompasses use of use of intact WT1 (see column 14, last paragraph). Chada et al. do not teach that the

peptide is 249 amino acids or longer, but less than full length WT1. Herlyn et al. disclose that amino acids 275-429 of WT1 encode a region that is similar to that found in normal protein Egr1 family, wherein it is desireable not to induce immunity against said region if it is desired to produce immunity specific for WT1 (see page 6, first paragraph). Therefore, a routineer would have used a peptide that did not contain said region (such as a peptide of the first 274 amino acids of WT1) in the method of Chada et al. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed method because Chada et al. teach the claimed method except that the peptide is 249 amino acids or longer, but less than full length WT1 whilst Herlyn et al. disclose that amino acids 275-429 of WT1 encode a region that is similar to that found in normal protein Egr1 family, wherein it is desireable not to induce immunity against said region if it is desired to produce immunity specific for WT1. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aformentioned to avoid generating an immune response against normal proteins wherein said response could have potentially deleterious effects.

14. Claim 56 is rejected under 35 U.S.C. 103(a) as being unpatentable over Berzofsky et al. (WO 94/21287) in view of Herlyn et al. (WO 95/29995).

Berzofsky et al. teach a method of cancer immunotherapy wherein immunogenic WT1 peptides which stimulate T cell responses are administered to a patient (page 4, first paragraph and claims 1, 5,11,16). Berzofsky et al. teach that said WT1 peptide is administered with a pharmaceutically acceptable carrier (see page 7, lines 1-2.). Berzofsky et al. teach that said WT1 peptide is administered with a non-specific immune enhancer (a dendritic cell). Berzofsky et al. teach that the aforementioned peptide can be used to treat the WT1 positive Wilms' tumor (see pages 14-16). Berzofsky et al. do not teach that the peptide is 249 amino acids or longer, but less than full length WT1. Herlyn et al. disclose that amino acids 275-429 of WT1 encode a region that is similar to that found in normal protein Egr1 family, wherein it is desireable not to induce immunity against said region if it is desired to produce immunity specific for WT1 (see page 6, first paragraph). Therefore, a routineer would have used a peptide that did not contain said region (such as a peptide of the first 274 amino acids of WT1)

in the method of Berzofsky et al. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed method because Berzofsky et al. teach the claimed method except that the peptide is 249 amino acids or longer, but less than full length WT1 whilst Herlyn et al. disclose that amino acids 275-429 of WT1 encode a region that is similar to that found in normal protein Egr1 family, wherein it is desireable not to induce immunity against said region if it is desired to produce immunity specific for WT1. One of ordinary skill in the art at the time the invention was made would have been motivated to do the aformentioned to avoid generating an immune response against normal proteins wherein said response could have potentially deleterious effects.

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
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Art Unit 1644